Current status of carotid bifurcation angioplasty and stenting based on a consensus of opinion leaders

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***Objective*: Carotid bifurcation angioplasty and stenting (CBAS) has generated controversy and widely divergent opinions about its current therapeutic role. To resolve differences and establish a unified view of CBAS' present role, a consensus conference of 17 experts, world opinion leaders from five countries, was held on November 21, 1999.**

***Methods:* These 17 participants had previously answered 18 key questions on current CBAS issues. At the conference these 18 questions and participants' answers were discussed and in some cases modified to determine points of agreement (consensus), near consensus, (prevailing opinion), or divided opinion (disagreement).**

***Results:* Conference discussion added two modified questions, placing a total of 20 key questions before the participants, representing four specialties (interventional radiology, seven; vascular surgery, six; interventional cardiology, three; neurosurgery, one). It is interesting that consensus was reached on the answers to 11 (55%) of 20 of the questions, and near consensus was reached on answers to 6 (30%) of 20 of the questions. Only with the answers to three (15%) of the questions was there persisting controversy. Moreover, both these differences and areas of agreement crossed specialty lines.**

***Consensus Conclusions:* CBAS should not currently undergo widespread practice, which should await results of randomized trials. CBAS is currently appropriate treatment for patients at high risk in experienced centers. CBAS is not generally appropriate for patients at low risk. Neurorescue skills should be available if CBAS is performed. When cerebral protection devices are available, they should be used for CBAS. Adequate stents and technology for performing CBAS currently exist. There were divergent opinions regarding the proportions of patients presently acceptable for CBAS treatment (<5% to 100%, mean 44%) and best treated by CBAS (<3% to 100%, mean 34%). These and other consensus conclusions will help physicians in all specialties deal with CBAS in a rational way rather than by being guided by unsubstantiated claims. (J Vasc Surg 2001;33:S111-6.)**

Carotid bifurcation angioplasty and stenting (CBAS) represents a relatively new and controversial treatment for patients with atherosclerotic lesions at the junction of the common and internal carotid arteries. Balloon angioplasty has been used sporadically for many years to treat patients with carotid bifurcation stenoses.[1,2] However, it was only after intravascular stents became available that any enthusiasm was generated for the endovascular management of these lesions.[3-6] Despite the fact that angiographically favorable results were often achieved, the procedural stroke rates in many of the earlier series remained higher than those for carotid endarterectomy.[5-7] Moreover, angioplasty and stenting of carotid bifurcation lesions in an ex vivo system has been shown to generate large amounts of intraluminal particulate debris.[8] Nevertheless, with better selection of patients and improved technology, lower periprocedural stroke rates were observed with CBAS.[9,10] As a result, some workers have proclaimed that CBAS is currently equivalent to or superior to carotid endarterectomy (CEA) and that CBAS should be widely practiced and used to treat patients with carotid stenoses. This has led to much controversy and equally strong recommendations by others that CBAS not be used widely and that recommendations to do so are inappropriate and unethical at this time.[7,11,12] In most of the conflicting reports on this topic, there is far more opinion than data. The result is that the medical profession at large is left confused by the conflicting claims and recommendations of the overenthusiastic supporters or rabid detractors of CBAS. Accordingly, they have difficulty in determining what treatment is best for their patients, and they cannot provide them with rational recommendations.

To resolve some of the controversy and conflicting

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Table I. Listing of the 17 consensus participants, their specialty affiliation, and their home country

Radiologists		*Cardiologists*		*Surgeons*	
Bolia*	USA	Henry*	France	Beebe	USA
Connors*	USA	Roubin*	USA	(Bell)‡	UK
Ferguson*	Canada	Yadav*	USA	Bergeron*	France
(Katzen)*	USA			Diethrich*	USA
(Matthias)*	Germany			Hobson	USA
(Theron)*	France			Hopkins*†	USA
(Wholey)*	USA			Ohki*	USA

Names in parentheses indicate those who contributed to the questionnaire but were unable to attend the oral session.
*Major endovascular therapist.
†Neurosurgeon.
‡Represented at oral conference by Dr. Bolia.

recommendations regarding CBAS, it was decided to hold a conference of opinion leaders on this topic. The purpose of this consensus conference, which included experts from several disciplines interested in this new method of treating patients with carotid lesions, was to reach agreement or consensus on as many key issues related to this new treatment modality as possible. This article summarizes the results of this consensus-seeking process and should provide a balanced overview of CBAS and its current role in the treatment of patients with carotid bifurcation lesions. This information should prove valuable to the medical community at large in their efforts to apply this new treatment rationally and appropriately to patients with carotid bifurcation stenosis caused by arteriosclerosis.

METHODS

To provide the most informed, balanced overview of the topic, the consensus conference organizers (F.J.V. and M.A.) selected as participants those individuals who were generally acknowledged to be the best and brightest leaders in the field. This meant those physicians who, irrespective of the specialty they represented, had the widest experience and greatest interest in CBAS. Seventeen participants were chosen from four different specialties (Interventional Radiology, Interventional Cardiology, Vascular Surgery, and Neurosurgery) and five different countries (United States, United Kingdom, Canada, Germany, and France). As shown in Table I, seven of these participants were interventional radiologists, three were interventional cardiologists, and seven were surgeons (six vascular surgeons and one neurosurgeon). All 17 participants had a clear endovascular orientation, and all but three were major endovascular therapists. Thus the conference participants were unlikely to represent the views of "surgical foxes guarding the carotid stenosis henhouse," as one participant had worried about when the conference was in the planning stage. All conference participants had performed clinical or laboratory studies of CBAS and had published and lectured widely on this topic. All 17 of the selected participants agreed to take part in the consensus process.

Before the Oral Consensus Conference

All 17 participants were sent a questionnaire requesting their responses to 15 key questions relating to the present status of CBAS. These questions were designed to evaluate current points of agreement or disagreement about the present role of CBAS in medical practice. The answers to these questions plus discussion of these questions and their answers at the oral consensus session would serve as a major basis for the written documentation that would result from the consensus process. The questionnaire had room for comments in addition to the "yes," "no," or "uncertain" answers that were possible for most of the questions. All 17 participants returned their completed questionnaire in time for the answers to be collated and analyzed before the oral session. Thus the answers to the questions could be discussed effectively at the oral session. In addition, one of the participants believed that an additional three questions should be asked, answered, and discussed at the oral session so that a better, more complete overview of CBAS might be obtained. These three questions were also circulated and answered by all 17 participants. Analysis of these three additional questions were also completed so that they could be discussed at the oral session.

Oral Consensus Conference

This conference was held in New York City on November 21, 1999. Twelve participants in addition to Drs. Veith and Amor attended. Five participants were unable to attend because of previous commitments or urgent conflicts. One absent participant's views were represented at the oral session by his colleague who was in attendance (Amman Bolia for Peter Bell). Questions and comments from an audience of 250 interested physicians were also entertained by the oral session participants.

The oral session consisted of a 10-minute introductory statement outlining the purpose and structure of the oral session and the documentation that would result. A summary and analysis of the answers to each of the 18 questions asked in the questionnaires was then presented. Discussion of each question and its answers then followed.

In some cases questions were modified to permit answers on which most participants could agree. In other instances participants' answers were changed as the question was clarified by the discussion. An effort was made by all to reach consensus or near consensus on as many aspects of CBAS as was currently possible.

After these discussions of each question, each of the 12 participants in attendance presented a 5- to 10-minute oral summary of the key points he wished to make on the topic. Each presentation was discussed by the other participants present. Again, a major goal of all present was to resolve areas of disagreement, if possible.

Written Documentation of the Consensus Process

This article summarizes the participants' responses to the 18 questions originally posed and the two modifications to these questions and their answers that were arrived at during the discussion at the oral consensus conference. Based on these answers and the accompanying discussion, this article will also provide a broad overview-summary of the current, generally agreed-on role of CBAS in the treatment of patients with carotid bifurcation stenosis. And finally, it will provide a summary-discussion of the authors' views and predictions of the future role of CBAS in the treatment of patients with carotid disease and what questions must be answered for that role to be determined.

In addition to this article, a book will be published representing the results of the consensus process in greater detail. Also included in this book will be a series of articles from 14 of the 17 consensus participants. As part of the consensus process, all these participants were asked to write these articles, which would summarize their personal experience with CBAS and their current opinions and future predictions about its place in the treatment of patients.

DEFINITIONS

Answers to all questions were collated and analyzed according to the following definitions (Table II). If 12 or more of the 17 responding participants agreed on a response to a question about CBAS, that answer was considered to represent consensus or general agreement. If 10 or 11 of the 17 respondents agreed on a response, that response was considered to represent near consensus or prevailing opinion. Near consensus was also reached when nine respondents agreed on a response while two or three were uncertain and five or six disagreed. If only nine or fewer of the 17 participants agreed on a response to a question, that response was considered an area of divided opinion, disagreement, or uncertainty.

Table II. Definitions of the criteria for determining the results of the consensus process

- 17 Respondents
- ≥12/17 = Consensus (agreement)
- 10-11/17 = Prevailing opinion (near consensus) (or 9/17 + 2-3 uncertains)
- < 9/17 = Divided opinion/disagreement/uncertainty

All of the original 18 questions had answers from all 17 participants. The two derivative questions had responses from the 13 participants represented at the oral consensus conference.

RESULTS

A. Overall Results Of the 18 questions originally posed to the conference participants, consensus or agreement with regard to the answer was attained on nine and near consensus or prevailing opinion on six. The answers to the three remaining original questions reflected divided opinion or wide ranges of opinion based on conflicting views, uncertainty, or actual disagreement. In addition, at the oral session two derivative or altered questions were posed. With these minor alterations in the question, the answers were converted from "prevailing opinion" to consensus. Thus consensus was reached on 11 of 20 or 55% of the answers to key questions posed, and near consensus was reached on 6 of 20 or 30% of the answers. Only in the answers to 3 of the 20 or 15% of the questions was there a wide range of divergent opinions. These overall results reflect a remarkable degree of agreement among the experts on this controversial topic.

B. Consensus or Agreement Reached The conference participants reached consensus or agreement on answers to the following 11 questions relating to crucial issues concerning CBAS.

1. Should CBAS undergo widespread practice (ie, be standard of care) currently? Of the 17 respondents, 14 answered no. Two others who voted yes would advocate use of CBAS only for specific indications or surgically unfit patients. Otherwise, these two participants, one a radiologist and one a surgeon, would have voted no. Thus clear consensus was reached that CBAS should not currently be recommended for widespread practice, that is, become the standard of care.

2. Should widespread (ie, standard of care) CBAS await results of randomized studies? Of the 17 participants, 12 answered yes. One respondent, a radiologist, would vote yes if the question was not applied to patients at high risk for whom he deemed registries to be adequate. Thus consensus was reached that widespread application of CBAS should await the results of randomized prospective trials.

3. Is CBAS currently appropriate only for low risk (NASCET eligible) patients? Of the 17 participants, 16 answered no. Thus clear consensus was reached that CBAS should not currently be considered appropriate only for patients at low risk. Parenthetically, one respondent commented that the CREST Trial should

be performed only after high-risk registry results were available.

4. Must high-level neurointerventional skills and techniques be available to perform CBAS? Of the 17 participants, 12 answered yes, 3 (2 cardiologists and 1 surgeon) answered no, and 2 (surgeons) were uncertain. One surgeon commented that the skills and techniques need not be possessed by the CBAS operator but should be available within the same institution. Thus consensus was reached that high-level neurorescue skills and techniques must currently be available to perform CBAS.

5. Is the optimal stent for use in CBAS currently defined? Of the 17 participants, 13 answered no, 1 surgeon answered yes, and 3 (2 radiologists and 1 surgeon) indicated their uncertainty. Thus consensus was reached that the optimal stent for use in CBAS was not currently defined.

Despite this, one cardiologist commented that current stents were adequate, and one surgeon commented that nitinol stents will probably replace stainless steel stents.

6. Assuming comparable immediate and late results between CBAS and carotid endarterectomy (CEA), should CBAS be offered to patients in some circumstances? Of the 17 participants, 14 answered yes. Three respondents (one radiologist and two surgeons) answered no. However, four respondents who acknowledged that there were currently no data to justify the assumption implied in this question. Nevertheless, consensus was reached that if the assumption of equivalent results for CBAS and CEA could be shown, then CBAS should be offered to patients in some circumstances.

7. Would you offer CBAS to patients in all possible circumstances in which treatment of carotid stenosis was indicated? Of the 17 participants, 13 answered no. Thus consensus was reached that CBAS should not be offered to patients requiring treatment of carotid bifurcation stenosis in all circumstances. Three respondents commented that this could only be done when validated data were available to justify such practice.

8. In what circumstance is CBAS presently justified in experienced centers? Consensus was reached on five presently justifiable indications for CBAS in patients requiring treatment for carotid bifurcation stenoses. These were (1) high-risk* patients with symptoms, (2) recurrent stenosis, (3) previous radical neck dissection or cervical irradiation, (4) high* bifurcation or extent of the carotid lesion, and (5) indications for CEA, but patient unfit* for surgery. (* Term not specifically defined.)

In addition, the prevailing opinion (8 of 12 of those present at the oral session) was that CBAS was also justified in patients with indications for CEA in the presence of a contralateral internal carotid occlusion. A minority (4 of 12) of the participants, whose experience showed minimally increased risk of CEA in this circumstance, believed that this was not an indication for CBAS.

9. What conditions currently contraindicate CBAS? Consensus was reached on five current contraindications. These were (1) intraluminal thrombus, (2) complex* bifurcation lesions, that is, long multifocal lesion or an angulated internal carotid artery, (3) extensive* aortic or brachiocephalic trunk plaque; severe* tortuosity or calcification of the aortic arch vessels, (4) ringlike heavy calcification of the carotid bifurcation, (5) neurologically unstable patient or a stroke within 3 weeks of the intended CBAS (* term not specifically defined).

Young patients (<65 or <55 years of age) were also considered by some participants to be poor candidates for CBAS, but this contraindication was believed to be inappropriate by most who attended the oral session.

Consensus was also reached by participants at the oral session on two modified original questions that had been posed. Answers to the original questions were consistent with near consensus or prevailing opinion. However, a number of participants altered their answers with the modified questions to produce consensus. The modified questions and their consensus answers were as follows.

10. When cerebral protection devices become available, CBAS should only be performed with some form of such device? All 12 of the oral session participants agreed (clear consensus) that when cerebral protection devices were available, they should be used for CBAS. However, three participants acknowledged that the value of these devices in lowering the incidence of periprocedural stroke has not been proven conclusively. The remaining participants believed that current evidence was adequate to mandate use of these devices when they are available.

11. Are adequate stents and technology for performing CBAS currently available, if cerebral protection devices were available and effective? Of the 17 participants, 12 answered this question yes, 4 answered no, and 3 were uncertain. Thus consensus was reached that adequate stents and technology are currently available for the performance of CBAS, when effective cerebral protection devices are included.

C. Near Consensus or Prevailing Opinion Reached The conference participants reached near consensus or prevailing opinion on answers to the following questions.

1. Are the optimal techniques for performing CBAS currently defined? Of the 17 participants, 11 answered no and 6 answered yes. Thus the prevailing opinion was that optimal techniques for performing CBAS are not currently defined. One cardiologist commented that this was a technique in evolution. One radiologist indicated the need for more dedicated designs of stents and introducer devices for CBAS.

2. Is CBAS currently appropriate for high-risk patients only? Of the 17 participants, 11 answered yes and 6 answered no. Thus the prevailing opinion was that CBAS was currently appropriate only for patients at high risk. Conceivably, some of the respondents who voted no did so because they believed that CBAS should not be limited only to patients at high risk. If that were the case, it would only strengthen the prevailing opinion that CBAS was currently appropriate for patients at high risk.

One surgeon commented that there was, however, a need to define patients at high risk precisely. The affirmative answers to this question were given by four radiologists, one cardiologist, and six surgeons. The negative answers were given by three radiologists, two cardiologists, and one surgeon. Thus the prevailing opinion was expressed across specialty lines.

3. Is CBAS currently appropriate for high- and low-risk patients? Of the 17 participants, 10 answered this question no, 5 answered yes, and 2 were uncertain. Thus the prevailing opinion was that CBAS is not currently appropriate for patients at high and low risk.

Of the 10 negative answers, 3 were given by radiologists, 1 by a cardiologist, and 6 by surgeons. Thus again the prevailing opinion was expressed across specialty lines. The two uncertain answers were expressed by radiologists who believed that clinical trials were needed to define indications precisely.

4. For CBAS operators with complication rates equal to or better than guidelines for CEA, should they presently be able to offer their patients a carotid stenting option? Of the 17 participants, 11 answered this question yes and 6 answered no. Three of the individuals who answered negatively commented that there was insufficient valid comparative data in comparable patients to justify an affirmative answer. This lack of data was particularly evident with regard to late results. Nevertheless, the prevailing opinion was that CBAS operators with complication rates equivalent to those for CEA should presently be able to offer some patients a stenting option. Again, this prevailing opinion was expressed by individuals from all three specialties (five radiologists, three cardiologists, and three surgeons).

5. Should CBAS currently only be performed with some form of cerebral protection device? Of the 17 participants, 9 answered this question no, 5 answered yes, and 3 were uncertain. Thus the prevailing opinion was that CBAS currently can be performed without a cerebral protection device. It should be noted, however, that the European respondents largely answered yes to this question, probably because such devices are available to them. On the other hand, U.S. respondents tended to answer no because such devices are not presently available in the United States. It is also noteworthy that three participants (one radiologist, two surgeons) considered the value of cerebral protection devices unproven.

When the question was modified slightly (at the oral session [see consensus question 10]), clear consensus was reached that CBAS should only be performed with some form of cerebral protection device when such devices were available.

6. Are adequate stents and technology for performing CBAS currently available? Of the 17 participants, 10 answered yes, 4 answered no, and 3 were uncertain. Thus the prevailing opinion was that adequate stents and technology for performing CBAS are currently available. That opinion was expressed across specialty lines (four radiologists, two cardiologists, and four surgeons). When the question was slightly modified at the oral session to assume that effective cerebral protection devices were available, a consensus affirmative answer to this question was obtained (see consensus question 11).

D. Divided Opinion or Disagreement

1. Should a Food and Drug Administration Investigational Device Exemption (IDE) be required to perform CBAS in the USA - or comparable approval elsewhere? Of the 17 participants, 9 answered no and 8 answered yes. Thus opinion on this question was clearly divided. One surgeon commented that an IDE should be required except for an occasional case. One radiologist commented that IDEs should only be required during clinical trials. The eight affirmative answers were from three radiologists, one cardiologist, and four surgeons; the nine negative answers were from four radiologists, two cardiologists, and three surgeons. Thus there was no specialty bias for either answer. It is noteworthy that the Food and Drug Administration has indicated that performance of CBAS without an IDE is "in contravention of Food and Drug Administration regulations.[13]

2. What proportion of patients requiring treatment for carotid bifurcation disease are presently acceptable for CBAS? The 17 participants had a wide range of proposed percentages in answer to this question. These divergent opinions ranged from less than 5% to approximately 100%, with a mean of 44%. There was also a wide range of overlapping answers within each specialty, although the highest responses (>60%) were in the answers of the interventional specialists. Radiologists' answers were less than 5%, 6%, 15%, 80%, 90%, approximately 100%, and uncertain (mean 49%). Cardiologists' answers were 40%, 80%, and 95% (mean 72%). Surgeons answers were 5%, 10%, 20%, 20%, 35%, 60%, and uncertain (mean 25%).

3. What proportion of patients requiring treatment for carotid bifurcation disease are presently best or optimally treated by CBAS? Again, the 17 participants had a wide range of proposed percentages in answer to this question. These divergent

opinions ranged from less than 3% to approximately 100%, with a mean of 34%. Again, there was a wide range of overlapping answers within each specialty. Radiologists' answers were 3%, less than 5%, 15%, 45%, 90%, approximately 100%, and uncertain (mean 43%). Cardiologists' answers were 25%, 80%, and uncertain (mean 53%). Surgeons' answers were less than 3%, less than 5%, 5%, 15%, 20%, 25%, and 50% (mean 18%).

DISCUSSION

The consensus process brought together 17 of the world' s leading experts on CBAS. These 17 were asked key questions regarding the procedure and its present role in treating patients with carotid bifurcation arteriosclerosis. All 17 expressed themselves willingly and freely.

All who participated in this consensus endeavor on CBAS believed that the effort was worthwhile. Although widely divergent opinions exist between individuals and specialties with regard to this topic, all who took part in the consensus process were surprised by the degree of consensus and near consensus that existed when the experts in the field answered specific key questions and discussed both the questions and individual answers and interpretations of these answers. Even though there were a few differences of opinion and areas of disagreement and uncertainty, these were far outweighed by the points of clear agreement (consensus) and prevailing opinions (near consensus). It was also surprising to note that differences of opinion within the three specialties that were represented in the consensus process were far greater than differences of opinion between these three specialties. The one exception to this was a tendency toward the more liberal application of CBAS by the interventional specialists than by the surgical specialists, although again, there was considerable overlap between the specialties.

Even though these conference participants included enthusiastic supporters of wider adoption of CBAS, consensus was reached that clinical use of the procedure should currently be restricted to patients at high risk. It was further agreed that widespread practice of CBAS in patients at low risk should await the results of randomized prospective clinical trials comparing CBAS with CEA. It was also agreed that CBAS would almost certainly have a role in clinical practice, but precise definition of that role awaits further clarification. It was also agreed that CEA would have an important role in the treatment of patients with carotid bifurcation disease, although opinions varied greatly on what that role may be. The conference participants also agreed on the importance of cerebral protection in CBAS. Because embolic particles are universally generated by the procedure,[8] all agreed that some method to intercept these particles must be used. However, again, precise definition of which type of cerebral protection device (distal balloon, filter, or proximal balloon catheter) will prove to be best remains to be determined.

Thus the consensus process revealed that we are at the beginning of an exciting new treatment, CBAS. Much remains to be learned about this treatment, how it should best be performed, what stent or stents will be best, and where it will fit into the treatment of patients with carotid disease. However, it is clear that CBAS is currently justified for certain specific indications, that it should be evaluated in other circumstances by appropriate prospective trials, and that it will continue to generate interest and controversy for some time to come. However, for the present, it is hoped that the agreement reached in the consensus process will help to guide medical practitioners throughout the world in the appropriate and cautious application of this new technology. By using the information derived from this consensus conference, physicians can apply this technology more rationally and treat their patients better in an effort to prevent strokes.

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